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10/559,533	12/02/2005	Tadashi Okiyama	057788-0318680	9144

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EXAMINER

PATEL, SHEFALI DILIP

ART UNIT	PAPER NUMBER
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3767

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05/07/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/559,533	Applicant(s) OKIYAMA, TADASHI	
	Examiner SHEFALI D. PATEL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-11, 15-19 and 21-27 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 15, 16 and 21-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgments

1. In the reply, filed on February 5, 2010, Applicant amended claims 1, 15, and 21.
2. Applicant added new claims 25-27.
3. Currently, claims 1-5, 7, 15, 16, and 21-27 are under examination.

Claim Objections

4. Claims 1, 15, and 21 are objected to because of the following informalities:

In regards to claims 1, 15, and 21, in the new limitation “circulating plate” should be corrected as “circulating plate portion” in order to be consistent with the term “a plate portion” of the circulating member introduced before.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 15, and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In regards to claims 1, 15, and 21, the new limitation that “at least a portion of an exposed back surface of the septum is in contact with at least a portion of the circulating first fluid redirected by the circulating plate” appears to be new matter as the limitation is not stated or described in the specification at all.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 15, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claims 1, 15, and 21, the new limitation that “at least a portion of an exposed back surface of the septum is in contact with at least a portion of the circulating first fluid redirected by the circulating plate” is indefinite as it is unclear what element the back surface is exposed to (i.e. to the outside environment, to the interior of the port, etc.).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-3, 7, 15, 16, 21-23, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin (US 5,961,497), and further in view of Cote (US 5,775,671).

In regards to claims 1, 15, and 23, Larkin teaches a mixture injection port (Figures 1-3) comprising:

- a. a channel tube unit (connector [10])
- b. a septum (seal [70]) covering one end of the channel tube unit [10] and having a slit (slit [74]) into which a tube member (cannula assembly [12]) is inserted

Larkin does not teach a circulating member provided in the channel tube unit [10] below the septum [70], the circulating member being separate from the channel tube unit. Cote teaches a mixture injection port (Figures 1, 2A, 3 and 4) with a circulating member (actuator [50]) that is separate from a channel tube unit (housing components [26][36]). The circulating member [50] comprises a plate portion (transverse wall [60]) arranged to change direction of flow of a first fluid injected from an inserted tube member (nozzle [12]) or a second fluid flowing from the other end of the channel tube unit [26][36] and an edge portion (perimeter wall [52]) that protrudes upwardly from a periphery of the plate portion and is arranged along an inner wall of the channel tube unit. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the port, of Larkin, with a circulating member, as taught by Cote, as the circulating member will enhance the ability of the user to flush thoroughly the interior

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volume of the port by allowing fluid to pass through both the interior and exterior flow paths of the circulating member (Abstract)(column 1, lines 36-38)(column 5, lines 23-40).

In regards to claim 2, in a modified port of Larkin and Cote, Larkin teaches that the channel tube unit [10] comprises:

- a. a body portion (housing [24]) whose opening (opening [34]) is covered by the septum [70] and that is provided with an inner cavity (central passageway [26]) for accommodating the septum that is deformed by the insertion of the tube member [12] (Figure 2)
- b. a leg portion that is provided with a narrow tube portion (tube [16]) having a smaller width than that of the inner cavity [26], wherein the narrow tube portion is configured to provide communication between the inner cavity and the other end of the channel tube [10] (Figures 1-2)
- c. a step formed between the inner cavity [26] and the narrow tube portion [16] (Figures 1-2)

Larkin does not teach a plate portion of a circulating member that is mounted on the step. Cote teaches that the plate portion [60] of the circulating member [50] is mounted on a step (disc [40]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the step, of the modified port of Larkin and Cote, with a plate portion mounted on the step, as taught by Cote, as the plate portion will enhance the ability of the user to flush thoroughly the interior volume of the

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port by allowing fluid to pass through both the interior and exterior flow paths of the plate portion (Abstract)(column 1, lines 36-38)(column 5, lines 23-40).

In regards to claim 3, in a modified port of Larkin and Cote, Larkin does not teach a plate portion. Cote teaches that a groove (spaces in between raised areas [58]) is formed on a surface of the inner cavity side of the plate portion [60] of the circulating member [50], the groove extending in a direction different from a direction from which the first fluid is injected from the inserted tube member [12]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the plate portion, of the modified port of Larking and Cote, with a groove, as taught by Cote, as the plate portion will enhance the ability of the user to flush thoroughly the interior volume of the port by allowing fluid to pass through both the interior and exterior flow paths of the plate portion (Abstract)(column 1, lines 36-38)(column 5, lines 1-9)(column 5, lines 23-40).

In regards to claim 7, in a modified port of Larkin and Cote, Larkin does not teach a circulating member. Cote teaches that a groove (spaces in between castellations [54]) for guiding the first fluid or the second fluid is formed on an inner circumferential surface and an outer circumferential surface of the edge portion [52] of the circulating member [50]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the edge portion, of the modified port of Larking and Cote, with a groove, as taught by Cote, as the edge portion of the circulating member will enhance the ability of the user to flush thoroughly the interior volume of the port by

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allowing fluid to pass through both the interior and exterior flow paths of the circulating member (Abstract)(column 1, lines 36-38)(column 5, lines 23-40).

In regards to claim 16, in a modified port of Larkin and Cote, Larkin does not teach a circulating member. Cote teaches that a first groove (spaces in between raised areas [58]) is formed on a surface of the plate portion [60] of the circulating member [50] and a second groove (spaces in between castellations [54]) is formed on a surface of the edge portion [52] of the circulating member. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the circulating member, of the modified port of Larking and Cote, with first and second grooves, as taught by Cote, as the circulating member will enhance the ability of the user to flush thoroughly the interior volume of the port by allowing fluid to pass through both the interior and exterior flow paths of the circulating member (Abstract)(column 1, lines 36-38)(column 5, lines 1-9)(column 5, lines 23-40).

In regards to claims 21 and 22, Larkin teaches a method for transferring a fluid to or from a body through a mixture injection port (Figures 1-3), the mixture injection port comprising a channel tube unit [10] and a septum [70] covering one end of the channel tube unit and having a slit [74], the method comprising:

- a. inserting a tube member [12] into the slit [74] (Figure 1 to Figure 2)
(column 7, lines 61-63)

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- b. injecting a first fluid into the tube member [12] or a second fluid into an other end of the channel tube unit [10] (column 5, lines 8-20)(column 5, lines 30-35)
- c. circulating the first fluid or the second fluid towards the septum side (column 5, lines 8-20)(column 5, lines 30-35)
- d. guiding the first fluid to the other end of the channel tube unit [10] or the second fluid to a top portion of the tube member [12] (column 5, lines 8-20)(column 5, lines 30-35)

Larkin does not teach a circulating member provided in the channel tube unit [10] below the septum [70], the circulating member being separate from the channel tube unit. Cote teaches a mixture injection port (Figures 1, 2A, 3 and 4) with a circulating member (actuator [50]) that is separate from a channel tube unit (housing components [26][36]). The circulating member [50] comprises a plate portion (transverse wall [60]) arranged to change direction of flow of a first fluid injected from an inserted tube member (nozzle [12]) or a second fluid flowing from the other end of the channel tube unit [26][36] and an edge portion (perimeter wall [52]) that protrudes upwardly from a periphery of the plate portion and is arranged along an inner wall of the channel tube unit. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the port/method, of Larkin, with a circulating member, as taught by Cote, as the circulating member will enhance the ability of the user to flush thoroughly the interior volume of the port by allowing fluid to pass through both the interior and

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exterior flow paths of the circulating member (Abstract)(column 1, lines 36-38)(column 5, lines 23-40).

In regards to claims 25-27, in a modified port/method of Larkin and Cote, Larkin teaches that at least a portion of the exposed back surface of the septum [70] becomes exposed when the septum is deformed by insertion of the tube member [12] (Figure 2).

11. Claims 4, 5, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin and Cote, as applied to claim 2 above, and further in view of Arnett (US 5,817,069).

In regards to claims 4 and 24, in a modified port of Larkin and Cote, Larkin does not teach a circulating member. Cote does not teach that the plate portion [60] of the circulating member [50] is provided with a holding portion for engaging a narrow tube portion. Arnett teaches a mixture injection port (Figure 1, assembly [10]) wherein a plate portion (actuator [20]) is provided with a holding portion (second actuator end [98] and exterior surface [100]) for engaging a narrow tube portion (second end [32]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the plate portion, of the modified port of Larkin and Cote, with a holding portion, as taught by Arnett, as the holding portion of the plate portion will efficiently engage and position the plate portion with respect to the interior surface of the port (column 4, lines 8-26).

In regards to claim 5, in a modified port of Larkin, Cote, and Arnett, Larkin does not teach a plate portion. Arnett teaches a groove (second fluid passageway [106]: openings [108][110]) for guiding a first fluid or second fluid that is formed in the back face of the plate portion [20] and the holding portion [98][100] (Figure 1). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the plate portion and the holding portion, of the modified port of Larkin, Cote, and Arnett, with a groove, as taught by Arnett, as the groove of the plate portion and holding portion will allow fluid to freely flow through the groove from the inlet of the port to the outlet of the port in either direction (column 5, lines 25-32).

Response to Arguments

12. Applicant's arguments filed on February 5, 2010, have been fully considered but they are not persuasive:

In regards to claims 1, 15, and 21, Applicant argues that the combination of Larkin and Cote does not teach a mixture injection port including a septum and a circulating plate in which at least a portion of the exposed back surface of a septum is in contact with at least a portion of the circulating fluid redirected by a circulating plate (Reply, page 10). However, the combination of Larkin and Cote does teach said limitation: Larkin teaches a mixture injection port (Figures 1-3) including a septum [70] with an exposed back surface that becomes exposed when the septum is deformed by the insertion of a tube member [12] (Figure 2). Larkin does not teach a circulating plate. Cote teaches a mixture injection port (Figures 1, 2A, 3, and 4) with a circulating plate

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[50] that redirects fluid since fluid is caused to flow in two opposite directions (column 4, lines 55-63)(column 5, lines 30-37). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the port, of Larkin, with a circulating member, as taught by Cote, as the circulating member will enhance the ability of the user to flush thoroughly the interior volume of the port by allowing fluid to pass through both the interior and exterior flow paths of the circulating member (Abstract)(column 1, lines 36-38)(column 5, lines 23-40). Though neither Larkin nor Cote alone teaches a septum and a circulating plate, a person having ordinary skill in the art at the time the invention was made would recognize that in the combination port, of Larkin and Cote, fluid would be redirected in the opposite direction toward the exposed back surface of the septum via the circulating plate since the circulating plate would be positioned below the septum and the circulating plate allows fluid to flow in two opposite directions.

Applicant argues that "At most, the combination of Larkin and Cote might suggest engaging the lower extending skirt 17 having thread's 19 of the connector 10 of Larkin with the inlet section 16 provided with threads 14 of Cote. [See, e.g., Larkin, col. 5, lines 22-24 & Cote, col. 3, lines 40- 46 ("The inlet section 16 of the inlet housing component 26 is designed to accept a male Luer fitting 12 by tapering the inner surface 18 of the inlet section."); Fig. 1 (showing male Luer fitting 12 in phantom)]." (Reply, page 10). However, Examiner never suggested that the connector [10] of Larkin is connected to the inlet section [16] of the connector of Cote. Examiner proposed placement of the circulating plate [50], of Cote, into the port/connector [10], of Larkin: It would have been

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obvious to a person having ordinary skill in the art at the time the invention was made to modify the port, of Larkin, with a circulating member, as taught by Cote, as the circulating member will enhance the ability of the user to flush thoroughly the interior volume of the port by allowing fluid to pass through both the interior and exterior flow paths of the circulating member (Abstract)(column 1, lines 36-38)(column 5, lines 23-40).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/
Examiner, Art Unit 3767
05/05/2010

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